Safety of Spectacles for Children's Vision: A Cluster-Randomized Controlled Trial.

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Abstract (MUST be submitted as a separate file)

Purpose: To study safety of children's glasses in rural China, where fear that glasses harm vision is an important barrier for families and policy-makers.

Design: Exploratory analysis from a cluster-randomized, investigator-masked, controlled trial.

Methods: Among primary schools (n=252) in western China, children were randomized by school to one of three interventions: free glasses provided in class, vouchers for free glasses at a local facility or glasses prescriptions only (Control group). The main outcome of this analysis is uncorrected visual acuity after 8 months, adjusted for baseline acuity.

Results: Among 19,934 children randomly selected for screening, 5852 myopic (spherical equivalent refractive error <= -0.5 D) eyes of 3001 children (14.7%, mean age 10.5 years) had VA <= 6/12 without glasses correctable to > 6/12 with glasses, and were eligible. Among these, 1903 (32.5%), 1798 (30.7%), and 2151 (36.8%) were randomized to Control, Voucher and Free Glasses respectively. Intention-to-treat analyses were performed on all 1831 (96.2%), 1699 (94.5%), and 2007 (93.3%) eyes of children with follow-up in Control, Voucher and Free Glasses groups. Final visual acuity for eyes of children in the treatment groups (Free Glasses and Voucher) was significantly better than for Control children, adjusting only for baseline visual acuity (difference of 0.023 logMAR units [0.23 vision chart lines, 95% CI: 0.03, 0.43]) or for other baseline factors as well (0.025 logMAR units [0.25 lines, 95% CI 0.04, 0.45]).

Conclusion: We found no evidence that spectacles promote decline in uncorrected vision with aging among children.

Response to Reviewers

1. Revise Abstract to include 5 headings

Response: Done

2. Delete, "the authors have no other financial relationships with any organizations that might have an interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work" from Financial Statement.

Response: Done

Safety of Spectacles for Children's Vision: A Cluster-Randomized Controlled Trial

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Introduction

Some half of all disability among children in the developing world is due to poor vision.[1] The leading and most readily-treated cause of children's visual impairment (visual acuity <6/18) is refractive error, affecting 12.8 million children aged 5-15 years world-wide, half of whom live in China.[2] Chinese children, for whom uncorrected refractive error accounts for 90% of visual impairment, have among the world's highest rates of myopia (near-sightedness).[3, 4] Uncorrected refractive error is associated with worse self-reported visual function among children,[5] and provision of accurate spectacles improves children's functioning[6] and educational outcomes.[7] Spectacles provide an inexpensive and highly effective treatment for refractive error.

Despite the high prevalence and impact of children's refractive error in rural China, rates of spectacle ownership and wear remain as low as 15% among those needing them.[7] Studies in China[8-9] and elsewhere[10] suggest a major reason for this is the perception among children, parents and teachers that glasses wear harms children's vision by worsening myopia. Concerns about the safety of glasses wear for children also influences policy-makers. Government Health and Education Bureau websites in China may explicitly advise that children's glasses wear leads to vision problems,[11] or fail to recommend glasses as a treatment for myopia due to safety concerns.[12]

It is known that accurately-measured glasses improve the corrected visual acuity, but the concern among many laypersons in China is that wearing glasses will eventually worsen a child's uncorrected visual acuity, increasing dependence on their wear. It is this latter effect of glasses on the uncorrected vision which is not known. Previous small studies[13-5] have been inconclusive on the effect of glasses wear on refractive power, and have not compared wear of glasses with non-wear, or directly reported effects on visual acuity.

We carried out a large, cluster-randomized, population-based trial on the educational impact of providing spectacles to children with refractive error in rural China.[7] We now report an exploratory, intention-to-treat analysis of the impact of assignment to receive access to free spectacles on uncorrected (without glasses) VA over the course of a school year, approximately 8 months.

Methods

The protocol for this study was approved in full by Institutional Review Boards at Stanford University (Palo Alto, USA) and the Zhongshan Ophthalmic Center of Sun Yat-Sen University (ZOC, Guangzhou, China). Permission was received from local Boards of Education in each region, and the principals of all schools. The principles of the Declaration of Helsinki were followed throughout. The original trial (Registration Site: http://isrctn.org. Registration number: ISRCTN03252665) was designed to study the effect of providing free spectacles on children's educational performance, and found scores on a study-specific mathematic test were statistically significantly higher in the group receiving free spectacles compared to controls.[7]

The hypothesis of the current exploratory analysis, based on our original trial data, is that provision of glasses would slow the decline in uncorrected visual acuity (VA) expected to occur due to increase in myopia (near-sightedness) commonly observed among children with aging.[16] The primary outcome of the current analysis is uncorrected VA 8 months after provision of spectacles, adjusting for baseline VA. The choice of this outcome is based on the fact that uncorrected distance VA is expected to worsen with worsening myopia, and that vision itself, rather than refractive power, is the outcome of interest from the standpoint of disability and its alleviation. The methods of the original trial have been described previously[7] and are provided here for reference.

Setting, sampling and eligibility criteria

The study was carried out in two nearby areas of western China: Tianshui prefecture, a poor area in Gansu, one of China's poorest provinces[17-18] and Yulin prefecture, Shaanxi, a more affluent region in a middle-income province.[17, 19] One school from each township in both prefectures was randomly selected from a list of all primary schools, and within each school, one class was randomly chosen in each of the 4th and 5th grades. For the original trial, all children at the 252 selected schools meeting the following criteria were eligible:

- Uncorrected (without glasses) VA <= 6/12 in either eye
- Refractive error as follows:
  - Myopia <= -0.75 diopters (D)
  - Hyperopia >= +2.00 D or
  - Astigmatism (Non-spherical refractive error) >= 1.00 D
- VA could be improved to > 6/12 in both eyes with glasses

In the current analysis, carried out by eye rather than child, all non-myopic (refractive error > -0.5 D) eyes of eligible children were excluded. (Figure 1)

Questionnaires

At baseline (September 2012: beginning of the school year), enumerators administered questionnaires to children concerning their age, sex, glasses wear,

awareness of their refractive status, boarding at school and parental migration and education. A parental questionnaire asked about ownership of 13 selected items as an index of family wealth. Mathematics teachers were asked to state whether the blackboard was used for all teaching, most, about half, little or none. At closeout (May-June 2013: end of the school year) children again filled out a questionnaire on glasses wear. Population density was calculated as the total population divided by total land area at the township level.

Assessment of Visual Acuity

Children underwent baseline VA screening at school by a nurse and staff assistant, previously trained by optometrists from ZOC. VA was tested separately for each eye without refractive correction at 4 meters using Early Treatment Diabetic Retinopathy Study (ETDRS) charts[20] (Precision Vision, La Salle, IL, USA) in a well-lighted, indoor area. If the orientation of at least four of five optotypes on the 6/60 line was correctly identified, children were examined on the 6/30 line, 6/15 and then line by line to 6/3. If a line was failed, lines above were tested successively until the child identified 4 of 5 optotypes, with the VA for an eye defined as the lowest line read successfully. If the top line could not be read at 4 meters, the subject was tested as above at 1 meter, and the measured VA was divided by 4.

Refraction (Measurement of glasses power)

Children with uncorrected visual acuity <= 6/12 in either eye underwent cycloplegia with up to three drops of cyclopentolate 1% and automated refraction (Topcon KR 8900, Tokyo, Japan) with subjective refinement by a refractionist, previously trained by experienced pediatric optometrists from ZOC.

Randomization and Interventions

This was a cluster-randomized, controlled trial, with schools as the clusters. In October 2012, after the baseline survey and vision screening but prior to refraction, eligible children were randomized by school to receive one of three interventions (Figure 1):

- Free spectacles based on the child's measured refractive power dispensed at school by the study optometrist. (Free Glasses group, 84 schools);
- Vouchers bearing the child's name, school name and glasses prescription, exchangeable for free glasses at the local county hospital (distance from children's township: range 1-105 km, median 30 km). Parents were responsible for paying transportation costs. (Voucher group, 84 schools); or
- A glasses prescription and letter to the parents informing them of the refractive status of their child, with free glasses provided only at closeout, though this was not previously announced. (Control group, 84 schools).

Schools were stratified by size, county and number of children failing VA screening. We used R software (R Foundation for Statistical Computing, Vienna, Austria) to generate blocks of and randomly allocate schools within each block to the treatment arms.

Outcome Assessment

At closeout, VA was assessed using the protocol and vision chart described above. Spectacle wear was assessed through unannounced direct examinations on the same occasion. Children also described their own spectacle wear as "always," "only for studying" or “usually not worn". Study personnel were masked to group assignment. Participants (students, parents and teachers) and enumerators were not informed of either the overall design of the study or the explicit treatment arm assignment. During this visit, all children provided information on parental spectacle wear, and their own time spent out of doors and in near/middle distance work, important determinants of myopia progression.[16, 21-22]

Statistical Methods

Family wealth was calculated by summing the value, as reported in the China Rural Household Survey Yearbook (Department of Rural Surveys, National Bureau of Statistics of China, 2013), of items on the list of 13 owned by the family. Refractive power was defined throughout as the spherical equivalent, the spherical power plus half the cylindrical power.

Randomization groups were compared by intention-to-treat (ITT) using multiple linear regression, with endline uncorrected VA (log of the minimum angle of resolution [logMAR]) as main outcome, and intervention arms and baseline uncorrected VA as covariates. Other baseline variables were also investigated as predictors for final VA, with the final model including intervention arms and variables associated with baseline VA at $p<=0.20$. Student and school were included in a random intercept model to adjust for the correlation between eyes of a student, between children in the same school and between schools within the same randomization block. All analyses were performed using Stata 12.0 (StataCorp, College Station, TX), and SAS 9.3 (SAS Institute, Cary, NC, USA).

Results

Among 19,934 children screened at 252 selected schools, 4839 (24.3%) failed VA screening and were randomized (Figure 1). A total of 3177 (65.4%) children (6354 eyes) in 251 schools were eligible for allocation (VA improving with refraction). Among these, 5852 eyes (91.9%) of 3001 children (89.4%) were myopic; their baseline characteristics by treatment group are described in Table 1.

Intention-to-treat analyses were performed on all 1831 (96.2%), 1699 (94.5%) and 2007 (93.3%) eyes of children completing final VA assessment in the Control, Voucher and Free Glasses groups. (Figure 1) Those with follow-up did not differ in any baseline variables compared to those without (data not shown).

Table 2 gives the baseline, endline and change in uncorrected VA by intervention group, as well as the effect on endline VA adjusted for baseline VA of membership in the Voucher and Free glasses groups compared with the Control group. When children in the two treatment groups (Free Glasses and Voucher) were pooled, their endline VA adjusted for baseline VA was significantly better than for Control children by 0.023 (95% CI: 0.003, 0.043) logMAR units (0.23 lines on the VA chart). (Figure 2)

In multiple linear regression models (Table 3), better uncorrected endline VA was associated with: better baseline VA, membership in the Voucher Group or the combined treatment groups compared to the Control Group, male sex, and not wearing glasses at baseline (the latter presumably indicating that children with better VA were less likely to wear glasses). Students in the two treatment groups combined had on average 0.025 logMAR units better final VA (0.25 lines, 95% CI 0.04, 0.45, P = 0.02) compared to children in the Control group. Time spent in near work and outdoor activity, boarding at school, glasses wear by parents, parental education and migration status, province of residence, family wealth, use of blackboard in classroom teaching and population density of the township of residence were not significantly associated with endline VA.

Only 15% (441/3001) of these children needing glasses were wearing them at baseline. Endline glasses wear was 42% (observed: 439/1053) to 69% (self-reported: 730/1053) in the Free Glasses group; 38% (observed: 334/887) to 65% (self-reported: 574/887) among the Voucher group; and 26% (observed: 241/944) to 38% (self-reported: 355/944) among Controls.

Discussion

Results from intention-to-treat analysis in this randomized trial suggest that provision of spectacles does not promote the decline in uncorrected VA expected from increasing myopia with age[16] among children. Concern over such potential harm is widespread in China,[8-10] and has been identified as an important barrier to use of glasses by children needing them there[8-9] and elsewhere.[23-4]

This study provides the strongest evidence to date of the visual safety of spectacle wear for children. While the mean beneficial effect on VA of one-quarter line over a school year was modest, this effect size reflects all children randomized to receive treatment, whether glasses were used or not. Compliance rates in the treatment groups were 40-70% and conversely, a quarter to a third of children in the Control group had obtained glasses by the time of the final examination. Strategies to improve spectacle compliance could realize a greater impact on vision protection. We are currently testing teacher incentives as a means to improve children's classroom wear of glasses in a trial in Shanghai. The cumulative impact on vision protection over time may also be greater, though studies are needed to confirm this.

We searched the PubMed database in January 2014 for articles describing randomized trials in any language published since 1970, using the terms "correction," "glasses" and "spectacles" cross-indexed with "refractive error" and "myopia"; "change," "decline," "effect" and "impact;" and "vision" and "visual acuity." Two previous small (total of < 200 children) trials[14-5] compared the effect on change in refractive power over 18-24 months of full correction of refractive error with glasses to provision of glasses with power lower by 0.50-0.75 D than needed for optimal distance VA. The hypothesis of these studies was that lower-power glasses would be protective against the worsening of myopia with aging. The two studies actually found less progression of refractive error in the full-power group by 0.15 D,[14-5] an effect that was significant when the results were pooled in a subsequent Cochrane review.[13] These studies did not randomize children to go without glasses altogether, report on VA or include many Chinese children (41 participants [44%] in Chung et al[15]). Current sparse trial evidence is thus consistent in suggesting that correction of refractive error with glasses may be protective against, or us at least unlikely to worsen, declines in VA due to myopic progression with aging in children.

The factors underlying this tendency for myopia to worsen with age are not fully understood, but are thought to be controlled by dopaminergic pathways,[25] mediated by factors including time spent in near work and outdoors,[16, 21-2] and the stimulus of defocused light falling on the peripheral retina.[26] Wear of conventional spectacles does appear to contribute to this peripheral defocus,[27-8] which provided the impetus for the randomized trials of under-correction in preventing myopia progression as cited above.[14-5] The mechanism whereby spectacle wear (compared to non-wear)

appears in fact to retard worsening of vision associated with progression of myopia is not well understood.

Recent evidence suggests that optical correction designed specifically to prevent defocused light from falling on the peripheral retina may further retard age-related increase in myopic refractive error in children, when compared to conventional glasses and contact lenses.[29] These devices are still not widely available, and are quite expensive compared to conventional glasses. Though not at present appropriate for large-scale treatment programs, they may eventually offer an even greater vision protection benefit.

The strengths of the current study include its population-based sampling, randomized design and high follow-up rates, all of which increase confidence in the results. Weaknesses must also be acknowledged: VA not was not a pre-specified outcome of trial, compliance with spectacle wear was less than perfect and refractive power was not assessed at endline, precluding comparison of change in refractive power between groups over the study period. However, from the point of view of visual functioning and education, visual acuity rather than refractive error is the principal outcome of interest. All schools and children enrolled were drawn from two nearby prefectures in northwestern China, so that application of these findings to other settings must be made with caution.

Uncorrected refractive error is the leading cause of visual impairment among children world-wide.[2] The results of this study provide strong evidence of the visual safety of medium-term spectacle wear for myopic children. Taken together with the main trial result demonstrating statistically-significant improvements in educational outcomes with spectacle provision,[7] the current result provides further impetus for programs to provide spectacles for children needing them, particularly in China where the myopia problem is greatest.

Previous randomized studies in China have shown that interventions aimed at explaining to children, their teachers and parents that glasses wear is beneficial and safe have had no[30] or very modest[7] effects on uptake. A more immediate effect may be realized on policy-makers concerned over spectacle safety:[11-12] On the basis of our results to date,[7] authorities in Shaanxi and Gansu Provinces, where the study was conducted, have already authorized county-wide models of free glasses distribution, with potential for expansion throughout both provinces.

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Data sharing: The full dataset and statistical code are available at www.stanford.edu/REAP with open access The presented data are anonymized and risk of identification is low.

References

1. India 2001 census. Dimension of Disability in India, chapter 4. http://mospi.nic.in/Mospi_New/upload/disablity_india_statistical_data_11mar2011/Chapter%204-Dimension_Disability.pdf. Table 4.3 (b). (Website last viewed 7 August 2015).

2. Resnikoff S, Pascolini D, Mariotti SP, Pokharel GP. Global magnitude of visual impairment caused by uncorrected refractive errors in 2004. Bull World Health Organ. 2008;86(1):63-70.

3. He M, Zeng J, Liu Y, Xu J, Pokharel GP, Ellwein LB. Refractive error and visual impairment in urban children in southern china. Invest Ophthalmol Vis Sci. 2004;45(3):793-9.

4. He M, Huang W, Zheng Y, Huang L, Ellwein LB. Refractive error and visual impairment in school children in rural southern China. Ophthalmology. 2007;114(2):374-82

5. Congdon NG, Wang Y, Song Y et al. Visual disability, visual function and myopia among rural Chinese secondary school children: the Xichang Pediatric Refractive Error Study (X-PRES) Report #1. Invest Ophthalmol Vis Sci. 2008;49(7):2888-94.

6. Esteso P, Castanon A, Toledo S, et al. Correction of Moderate Myopia Is Associated with Improvement in Self-Reported Visual Functioning among Mexican School-Aged Children. Invest Ophthalmol Vis Sci. 2007;48(11):4949-4954.

7. Ma X, Zhou Z, Yi Het al. Effect of providing free glasses on children's educational outcomes in China: cluster randomized controlled trial. *BMJ* 2014;349:g5740.

8. Congdon N, Zheng MW, Sharma A et al. Prevalence and determinants of spectacle nonwear among rural Chinese secondary schoolchildren: The Xichang Pediatric Refractive Error Study Report 3. *Arch Ophthalmol.*

2008;126(12):1717-1723.

9. Li L, Lam J, Lu Yet al. Attitudes of students, parents, and teachers towards glasses use in rural China. *Arch Ophthalmol*. 2010;128(6):759-65.

10. Odedra N, Wedner SH, Shigongo ZS, Nyalali K, Gilbert C. Barriers to spectacle use in Tanzanian secondary school students. *Ophthalmic Epidemiol*. 2008;15(6):410-7

11. Fuxin Educational Network. "A letter to the parents and students in the city on National Eye Health Day." http://www.fxedu.com.cn/bencandy.php?fid=491&id=9417. (In Chinese) (Website last accessed 7 August 2015).

12. Beijing Education Bureau. "The Bureau's Recommendations for Young Glasses Wearers and the Young Obese."

http://edu.ifeng.com/gundong/detail_2011_08/12/8365849_0.shtml. (In Chinese). (Website last accessed 7 August 2015).

13. Walline JJ, Lindsley K, Vedula SS, Cotter SA, Mutti DO, Twelker JD. Interventions to slow progression of myopia in children (Review). *Cochrane Database of Systematic Reviews.* 2011, (12): CD004916.

14. Adler A, Millodot M. The possible effect of under-correction on myopic progression in children. *Clin Exp Optom.* 2006;89(5):315-21.

15. Chung K, Norhani M, O'Leary DJ. Under-correction of myopia enhances rather than inhibits myopia progression. *Vision Research* 2002.42(22):2555-59.

16. Morgan IG, Ohno-Matsui K, Saw SM. Myopia. *Lancet*. 2012;379(9827):1739-48.

17. Wikipedia list of Chinese administrative divisions by GDP per capita in 2012. http://en.wikipedia.org/wiki/List_of_Chinese_administrative_divisions_by_GDP_per_capita. (Website last accessed 7 August 2015).

18. Baidu Encyclopedia: Article on Yulin. http://baike.baidu.com/view/52250.htm. (In Chinese). (Website last accessed 7 August 2015.)

19. Baidu Encyclopedia: Article on Tianshui. http://baike.baidu.com/view/14548.htm. (In Chinese). (Website last accessed 7 August 2015.)

20. Ferris FL 3rd, Kassoff A, Bresnick GH, Bailey I. New visual acuity charts for clinical research. *Am J Ophthalmol*. 1982;94(1):91-6.

21. Rose KA, Morgan IG, Smith W, Burlutsky G, Mitchell P, Saw SM. Myopia, lifestyle, and schooling in students of Chinese ethnicity in Singapore and Sydney. Arch Ophthalmol. 2008;126(4):527-30.

22. Rose KA, Morgan IG, Ip J et al. Outdoor activity reduces the prevalence of myopia in children. Ophthalmology 2008;115(8):1279-85.

23. Khandekar R, Mohammed AJ, Al-Raisi A. Compliance of spectacle wear and its determinants among schoolchildren of Dhakhiliya region of Oman: A descriptive study. J Sci Res Med Sci. 2002;4(1-2):5-39

24. Wedner SH, Ross DA, Todd J, et al. Myopia in secondary school students in Mwanza City, Tanzania: the need for a national screening programme. Br J Ophthalmol. 2002;86(11):1200-6.

25. Stone RA, Pardue MT, Iuvone PM, Khurana TS. Pharmacology of myopia and potential role for intrinsic retinal circadian rhythms. Exp Eye Res. 2013;114:35-47.26. Smith EL. Optical treatment strategies to slow myopia progression: Effects of the visual extent of the optical treatment zone. Exp Eye Res 2013;114:77-88.

27. Berntsen DA, Barr CD, Mutti DO, Zadnik K. Peripheral defocus and myopia progression in myopic children randomly assigned to wear single vision and progressive addition lenses. Invest Ophthalmol Vis Sci 2013;54(8):5761-70.

28. Backhouse S, Fox S, Ibrahim B, Phillips JR. Peripheral refraction in myopia corrected with spectacles versus contact lenses. Ophthalmic Physiol Opt. 2012;32(4):294-303.

29. Sankaridurg P, Donovan L, Varnas S et al. Spectacle lenses designed to reduce progression of myopia: 12-month results. Optom Vis Sci 2010;87(9):631-41.

30. Congdon N, Li L, Zhang M et al. Randomized, controlled trial of an educational intervention to promote spectacle use in rural China: The See Well to Learn Well Study. *Ophthalmology* 2011;118(12):2343-50.

Figure Legends

Figure 1: Enrollment and progress of children through a randomized trial on the effects of the provision of spectacles to Chinese school-aged children

Figure 2. Change in visual acuity over one school year stratified by intervention group in a randomized trial on the effects of the provision of spectacles to Chinese school-aged children. Though higher values on the logMAR scale indicate worse vision, we have followed the convention in this figure that negative change indicates worsening and positive change indicates improvement.

A total of 10 outliers (4 Control, 6 Voucher/Free glasses) were excluded from the figure.

Table 1. Baseline characteristics of 5852 eyes of 3001 children with correctable myopia allocated in a trial of spectacle provision, by treatment group assignment.

Characteristic	Control Group	Voucher Group	Free Glasses Group	Treatment groups combined (Voucher + Free)	Missing data (%)
	n=1903*	n=1798*	n=2151*	n=3949*	
Age (years)	10.5 (1.1)	10.5 (1.1)	10.4 (1.1)	10.5 (1.1)	4 (0.07)
Male sex (%)	948 (49.8)	857 (47.7)	1040 (48.4)	1897 (48.0)	0 (0)
Degree of myopia (Diopters [D]):					0 (0)
<=-0.5 and >-1.0	182 (9.6)	206 (11.5)	265 (12.3)	471 (11.9)	
<=-1.0 and >-1.5	489 (25.7)	421 (23.4)	537 (25.0)	958 (24.3)	
<=1.5 and >-2.0	383 (20.1)	382 (21.2)	437 (20.3)	819 (20.7)	
<=-2.0	849 (44.6)	789 (43.9)	912 (42.4)	1701 (43.1)	
Baseline uncorrected visual acuity (LogMAR) †	0.6 (0.2)	0.6 (0.2)	0.6 (0.2)	0.6 (0.2)	0 (0)
Having glasses at baseline (%)††	270 (14.2)	262 (14.6)	349 (16.2)	611 (15.5)	0 (0)
Total time spent in near-work (hours/week)	7.3 (3.6)	7.5 (3.7)	7.4 (3.6)	7.5 (3.7)	4 (0.07)
Total time spent in middle distance activities (hours/week)	4.9 (4.2)	5.2 (4.3)	5.2 (4.5)	5.2 (4.4)	12 (0.21)
Total time spent in outdoor activities (hours/week)	7.9 (3.8)	8.0 (4.0)	8.0 (4.1)	8.0 (4.0)	11 (0.20)
Boarding at school (%)	442 (23.2)	336 (18.7)	546 (25.4)	882 (22.4)	3 (0.05)
One or more parents wearing glasses (%)	676 (35.6)	561 (32.7)	780 (36.3)	1372 (34.8)	14 (0.25)
One or both parents with >= 12 years of education (%)	384 (20.3)	315 (17.7)	490 (23.1)	805 (20.7)	58 (1.03)
Both parents out-migrated for work (%)	207 (11.0)	182 (10.2)	195 (9.2)	377 (9.6)	52 (1.03)
Gansu residence (%)	704 (37.0)	647 (36.0)	732 (34.0)	1379 (34.9)	0 (0)
Family wealth:					227 (4.04)
Bottom tercile	578 (32.0)	619 (36.2)	664 (31.9)	1283 (33.8)	
Middle tercile	659 (36.5)	567 (33.1)	643 (30.9)	1210 (31.9)	
Top tercile	567 (31.4)	525 (30.7)	775 (37.2)	1300 (34.3)	
Blackboard use in class:					0 (0)
Less than half of teaching	498 (27.0)	458 (26.6)	824 (40.0)	1282 (33.9)	
Half	780 (42.3)	700 (40.7)	645 (31.3)	1345 (35.6)	
More than half	567 (30.7)	563 (32.7)	590 (28.7)	1153 (30.5)	
Population density:					0 (0)
1st quartile	450 (23.7)	295 (16.4)	598 (27.8)	893 (22.6)	
2nd quartile	501 (26.3)	484 (26.9)	577 (26.8)	1061 (26.9)	
3rd quartile	343 (18.0)	467 (26.0)	459 (21.3)	926 (23.4)	
4th quartile	609 (32.0)	552 (30.7)	517 (24.1)	1069 (27.1)	

logMAR = log of the Minimum Angle of Resolution

*Data are presented as mean (SD) or number (%) unless otherwise stated.

† 0.1 change in logMAR indicates 1 line change on the vision chart.

†† Defined as having glasses at school at baseline, having previously been told to bring them to school.

Table 2. Effect of treatment arms in a trial of spectacle provision on final uncorrected visual acuity (LogMAR) of both eyes.

		Mean baseline uncorrected logMAR visual acuity (SD)	Mean endline uncorrected logMAR visual acuity (SD)	Unadjusted change in logMAR visual acuity (95% CI)	Effect of interventions on endline uncorrected visual acuity adjusted for baseline acuity (95% CI)*
Intervention group	N				
TOTAL	5537	0.59 (0.22)	0.71 (0.21)	-0.12* (-0.14, -0.10)	-
Control	1831	0.60 (0.22)	0.73 (0.21)	-0.13* (-0.15, -0.10)	(Reference)
Voucher	1699	0.58 (0.22)	0.70 (0.21)	-0.11* (-0.13, -0.09)	0.028* (0.004, 0.052)
Free Glasses	2007	0.59 (0.21)	0.71 (0.20)	-0.12* (-0.14, -0.10)	0.02 (-0.01, 0.04)
Treatment groups(Voucher + Free glasses) combined	3706	0.58 (0.21)	0.71 (0.20)	-0.11* (-0.13, -0.10)	0.023* (0.003, 0.043)

Though higher values on the logMAR scale indicate worse vision, we have followed the convention in this table that negative change indicates worsening and positive change indicates improvement

logMAR = log of the Minimum Angle of Resolution

* Indicates $P < 0.05$

SD Standard deviation 95%

CI Confidence Interval

Table 3: Linear regression model of potential predictors of final uncorrected logMAR* visual acuity.

Characteristics	Model adjusted only for baseline visual acuity (n=5537)		Full model‡ (n=5498)	
	Regression coefficient†¶ (95% CI)	P-value	Regression coefficient¶ (95% CI)	P-value
Baseline uncorrected visual acuity (LogMAR)	0.540 (0.520, 0.561)	< 0.001	0.515 (0.493, 0.537)	< 0.001
Intervention group (Control group as reference)				
Voucher Group	0.028 (0.004, 0.052)	0.02	0.029 (0.006, 0.053)	0.02
Free Glasses Group	0.018 (-0.005, 0.042,)	0.13	0.020 (-0.003, 0.044)	0.09
Treatment groups (Voucher + Free glasses)	0.023 (0.003, 0.043)	0.03	0.025 (0.004, 0.004)	0.02
Age (years)	-0.005 (-0.009, 0.0001)	0.06	-0.004 (-0.008, 0.001)	0.15
Male sex	0.015 (0.005, 0.024)	< 0.001	0.013 (0.003, 0.023)	0.01
Wearing glasses at baseline†	-0.049 (-0.064, -0.034)	< 0.001	-0.047 (-0.062, -0.032)	< 0.001
Total time spent in near-work (hours/week)	-0.0001 (-0.002, 0.001)	0.65		
Total time spent in midworking distance activities (hours/week)	0.001 (-0.0001, 0.002)	0.12	0.001 (-0.001, 0.002)	0.27
Total time spent in outdoor activities (hours/week)	0.001 (-0.0001, 0.002)	0.17	0.001 (-0.001, 0.002)	0.28
Boarding at school	-0.0001 (-0.014, 0.015)	0.98		

At least one other family member wearing glasses	-0.013 (-0.024, -0.003)	0.01	-0.010 (-0.021, 0.0001)	0.06
One or both parents with >= 12 years of education	-0.004 (-0.017, 0.008)	0.50		
Both parents out-migrated for working	0.002 (-0.014, 0.019)	0.78		
Gansu residence	0.024 (-0.005, 0.052)	0.11	0.021 (-0.006, 0.049)	0.13
Family wealth (Bottom tercile as reference)				
Middle tercile	-0.008 (-0.020, 0.005)	0.22		
Top tercile	0.008 (-0.005, 0.022)	0.21		
Blackboard use in class (Less than half as reference)				
Half	-0.015 (-0.031, 0.002)	0.08	-0.014 (-0.031, 0.002)	0.09
More than half	0.005 (-0.012, 0.023)	0.55	0.004 (-0.014, 0.022)	0.64
Population density (1st quartile as reference)				
2nd quartile	0.001 (-0.031, 0.033)	0.98		
3rd quartile	-0.013 (-0.048, 0.022)	0.31		
4th quartile	-0.015 (-0.050, 0.019)	0.61		

Though higher values on the logMAR scale indicate worse vision, we have followed the convention in this table that negative change indicates worsening and positive change indicates improvement

* logMAR = log of Minimum Angle of Resolution

† Except for the regression coefficient for baseline visual acuity (simple regression), coefficients for the different variables are for multiple models with endline visual acuity as dependent variable, adjusted for baseline visual acuity

‡Including variables associated with visual acuity p<= 0.20 in the model only adjusted for baseline visual acuity

¶ A negative regression coefficient indicates an association with worse endline visual acuity

CI Confidence Interval

Figure 1

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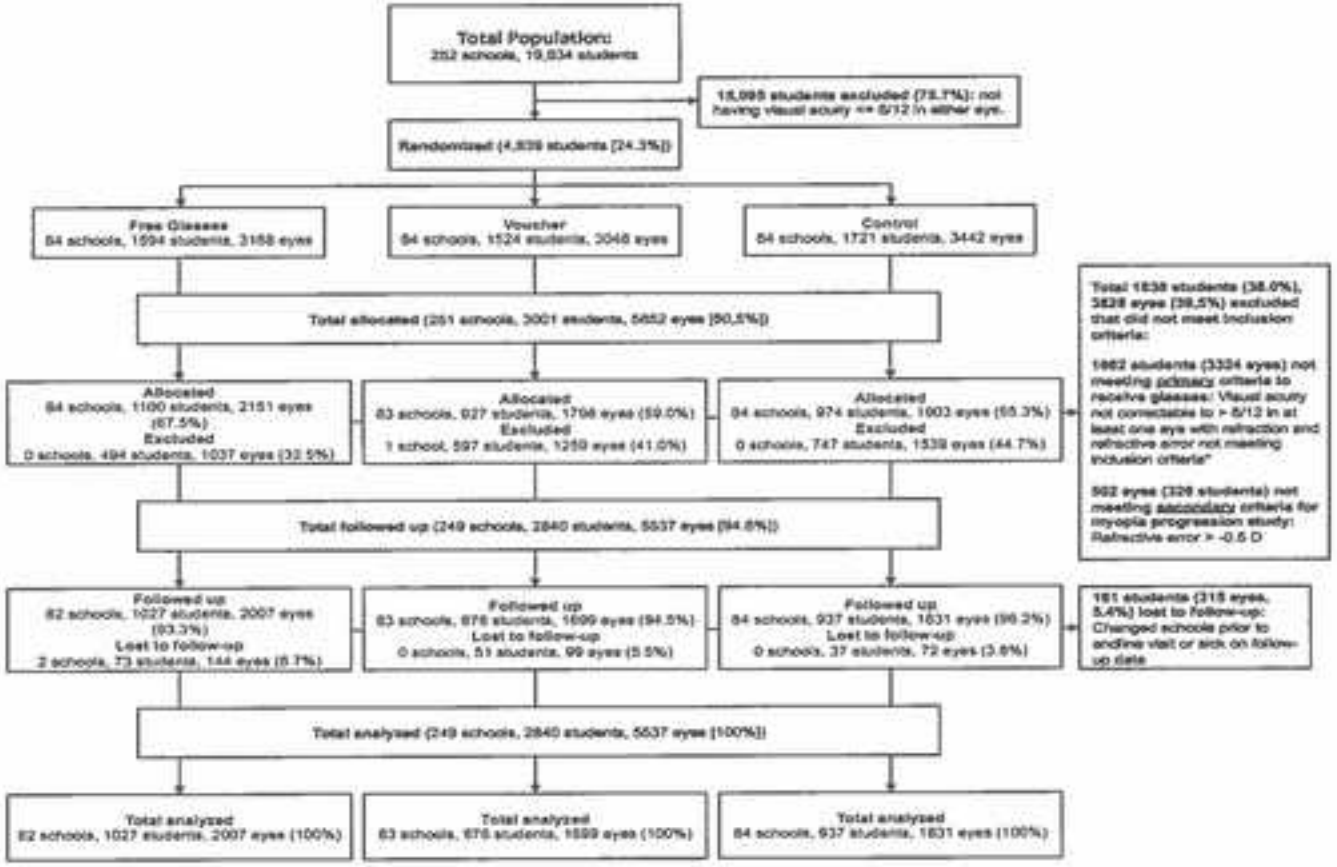

Figure 2

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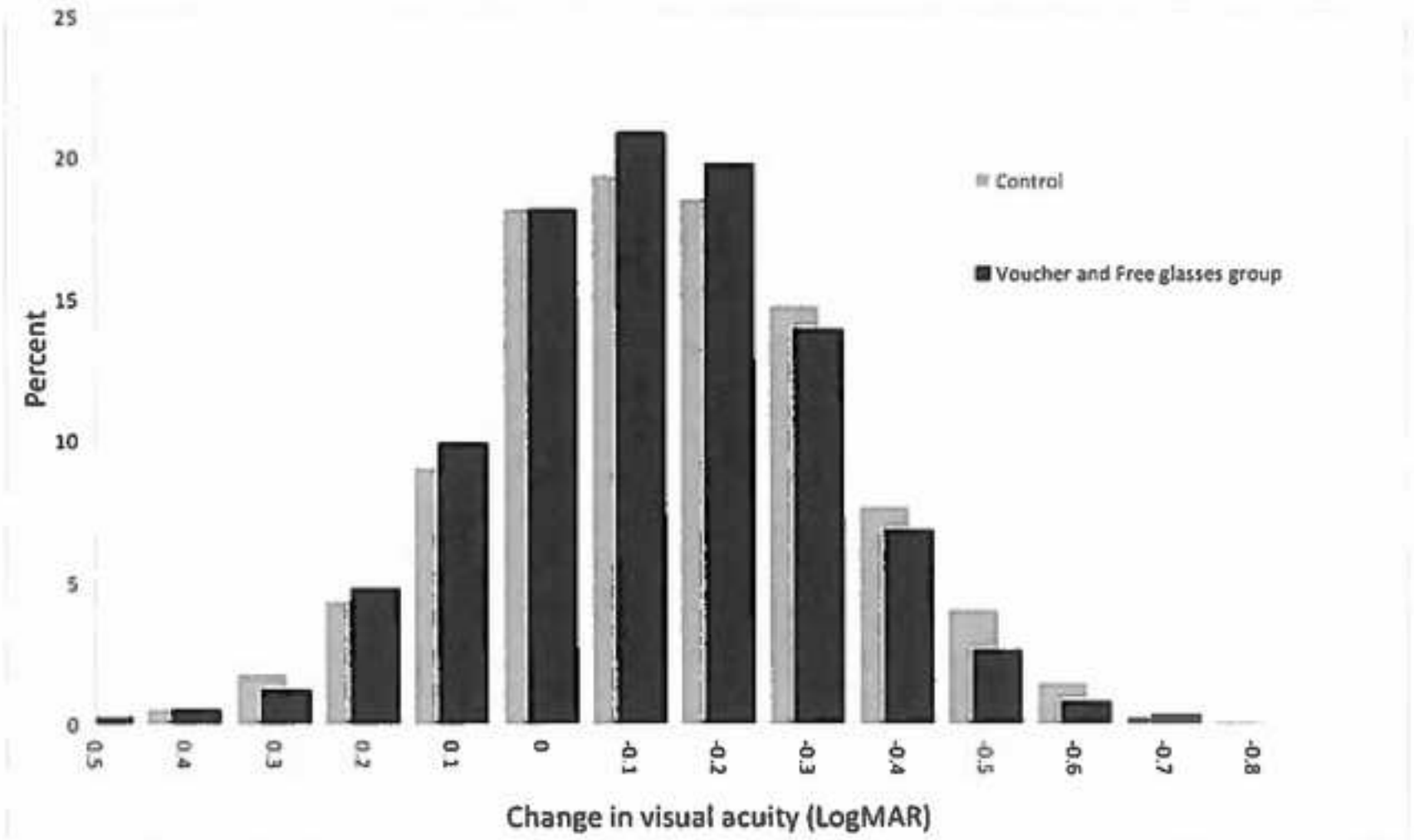

***Table of Contents Statement (Original Articles and Perspectives only)**

TOC Statement: Fear that glasses harms uncorrected visual acuity is a major barrier to children's wear in China. Our randomized trial including 20,000 children indicated that glasses do not promote decline in uncorrected vision with aging.

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CONSORT 2010 checklist of information to include when reporting a randomised trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11, Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	11, Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Recruitment : 7 Follow-up: 9
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 (22-23)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1, p. 11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12, Table 3 (26)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	12
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13-14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13-14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15
Other information			
Registration	23	Registration number and name of trial registry	Title page (1), Abstract (3)
Protocol	24	Where the full trial protocol can be accessed, if available	Provided as separate

			submission
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17